

### REMARKS

Claims 1-35 are presently pending in this application. By way of response on August 1, 2002, to the Restriction Requirement in Paper No. 8, Applicants elected to prosecute Group I claims, claims 1-19. In the Office Action issued by the Examiner on July 27, 2004, non-elected claims 20-33 were withdrawn from further consideration. In the present Amendment, Applicants have amended claims 1-19 and added new claims 34 and 35. Claims 34 and 35 were added to in order to properly claim the Markush groups listed in original claim 16. Therefore, claims 1-19, 34 and 35 are currently under consideration. No new matter is added to the application by way of the present Amendment.

### Priority

Applicants gratefully note the Examiner's acknowledgement of their claims for priority based on International Patent Application No. PCT/EP00/03844, filed on April 27, 2000, and German Patent Application No. 199 19 124.7, filed on April 21, 1999. Nonetheless, it is the Examiner's view that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(a)-(d), namely, that Applicants have not submitted either an English-language translation or a certified copy of the PCT/EP00/03844 application, and that Applicants have not submitted a certified copy of the 199 19 124.7 application.

Regarding the priority claim to International Patent Application No. PCT/EP00/03844, Applicants respectfully point out to the Examiner that the as-filed present application is an English-language translation of PCT/EP00/03844. Regarding German Patent Application No. 199 19 124.7, Applicants respectfully submit herewith a certified copy of German Patent Application No. 199 19 124.7. Accordingly, Applicants respectfully submit that the Examiner's objections based on the two priority documents have been overcome, and that Applicants are in compliance with 35 U.S.C. § 119.

Applicants respectfully direct the Examiner's attention to the front page of the "Non-Provisional Utility Patent Application Transmittal - 37 C.F.R. § 1.53(b)" for the present patent application, which contains priority claims to International Patent Application No. PCT/EP00/03844, filed on April 27, 2000, and to German Patent

Application No. 199 19 124.7, filed on April 21, 1999. Additionally, Applicants respectfully point out that the as-filed (unexecuted) Declaration contains the same priority information. Applicants also point out that prior application PCT/EP00/03844 properly claims priority to German Patent Application No. 199 19 124.7, filed April 21, 1999, in item number “(30)” on the front page of the International Application.

In further compliance with 35 U.S.C. §§ 119 and 120, Applicants have amended the specification, by way of the present Amendment, to recite the above-described priority information. Specifically, a paragraph setting forth the priority information has been inserted into the specification on page 1, immediately following the title of the invention.

Accordingly, Applicants respectfully submit that the instant application properly claims priority to PCT/EP00/03844, filed on April 27, 2000, and to German Patent Application No. 199 19 124.7, filed on April 21, 1999, and respectfully request the Examiner’s acknowledgement of the priority claim.

#### Specification

The Examiner objected to the specification for misrepresentations of the nature of a nucleic acid of the invention. Applicants thank the Examiner and have amended the specification herein to correct the misrepresentations at lines 8 and 10 of page 14 of the as-filed specification.

The Examiner also objected to the specification as allegedly lacking adequate antecedent basis for the claims. The Examiner’s objection is based on the claim language “that the nucleic acid molecule does not include the nucleic acid sequence of the ARO7 gene from *Saccharomyces cerevisiae*” in claim 1. While not necessarily agreeing with the Examiner’s reasoning, Applicants have amended the specification herein to contain the “negative limitation” claim language. Accordingly, Applicants respectfully submit that the specification indeed has sufficient antecedent basis for the pending claims.

Finally, the Examiner objected to the specification for failing to include BACKGROUND OF THE INVENTION, SUMMARY OF THE INVENTION, DETAILED DESCRIPTION, and BRIEF DESCRIPTION OF THE DRAWINGS section

headings. Accordingly, Applicants have amended the specification herein to contain the proper headings, as required by 37 C.F.R. § 1.77(b).

#### Claim Objections

The Examiner objected to claims 1-18 for not beginning with an article. Accordingly, Applicants have amended claims 1-18 to properly begin with an article.

The Examiner also objected to claim 19 as being in improper multiple dependent form. Accordingly, Applicants have amended claim 19 to be in proper dependent form. Applicants understand that the Examiner did not consider claim 19 on the merits because of this formality. Therefore, Applicants respectfully request that the Examiner now consider claim 19 on the merits. All arguments set forth herein apply with equal force to amended claim 19.

#### Rejection of claims 1-9 and 12-18 under 35 U.S.C. § 101

The Examiner rejected claims 1-9 and 12-18 because, in the Examiner's opinion, the claims are drawn to non-statutory subject matter. In particular, the Examiner rejected the claims as reading on naturally-occurring nucleic acids. The Examiner has kindly indicated that amendment of the claims to indicate that the claimed nucleic acids are "isolated" would be remedial for this rejection. While not necessarily agreeing with the Examiner's reasoning, Applicants have amended the rejected claims to indicate that the claimed nucleic acids are "isolated." Therefore, Applicants respectfully submit that the Examiner's rejection has been overcome and respectfully request reconsideration and withdrawal of the rejection.

#### Rejection of claims 1-18 under 35 U.S.C. § 112, first paragraph – written description

The Examiner rejected claims 1-18 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed (a "written description" rejection). The Examiner apparently rejects the claim language drawn to nucleic acids encoding fragments, variants, and homologs of SEQ ID NO:1, including those "having at

least 60% homology” to SEQ ID NO:1, because, in the Examiner’s view, the specification does not provide a representative number of species sufficient to convince the skilled artisan that the applicant is in possession of the claimed genus.

It appears to be the Examiner’s view that the disclosure only provides a “single species” that satisfies the written description requirement, and that the disclosure is solely to SEQ ID NO:1. Applicants respectfully disagree. Applicants respectfully remind the Examiner that the written description requirement may be satisfied by the presentation of a “representative number of species” of a genus, and that a representative number of species can be a single species where the skill in the relevant art and the predictability of the art is adequate. (Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement, Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, page 1106). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the *necessary common attributes or features* of the elements possessed by the members of the genus in view of the species disclosed. (Id.). Applicants submit that a common feature of the limited number of polynucleotides set forth in claims 1-18 is the property of such polynucleotides, when expressed in a cell, to produce a polypeptide having chorismate synthase activity. This common feature is clearly set forth in the instant application, and would therefore be readily understood by one of skill in the art.

While not necessarily agreeing with the Examiner’s reasoning, Applicants have amended claim 1 herein to remove all language directed to non-specific homologs, fragments and variants of SEQ ID NO:1. Specifically, Applicants have amended claim 1 to recite SEQ ID NO:1, complements of SEQ ID NO:1, nucleic acid sequences comprising SEQ ID NO:1, nucleic acid sequences that hybridize with such nucleic acids, and mutants of SEQ ID NO:1 wherein the mutant nucleic acids encode the same protein as does the SEQ ID NO:1 nucleic acid sequence, but differ in nucleic acid sequence from the wild type sequence due to the degeneracy of the genetic code.

Support for the amendments to claim 1 is found in the specification as filed on page 3, on page 4 in the definitions of “chorismate mutase” and “chorismate mutase activity,” in the hybridization conditions listed on pages 7 and 25, and in the

discussion of homologous sequences on pages 8 and 9. Specifically, these examples set forth the detailed steps required to identify or produce a nucleic acid of the present invention encoding a chorismate mutase polypeptide. Because the amendments to claim 1 and dependent claims 2-18 are fully supported in the specification as filed, these amendments therefore add no new matter.

Applicants respectfully submit that the functional language in claims 1-18 will also be understood by one of skill in the art to demonstrate Applicants' possession of the present invention at the time of filing, as such functional language, taken in conjunction with a chorismate mutase nucleic acid or polypeptide as set forth in the instant application, is evidence of sufficient identifying characteristics of the present invention.

Further, Applicants submit that one of ordinary skill in the art would understand Applicants to be in possession of any one of the species encompassed by the amended claims, as the skilled artisan would understand a nucleic acid of the claimed invention to necessarily encode a polypeptide that has the biological activity of a chorismate mutase as set forth in the present invention. Accordingly, one of ordinary skill in the art would understand the nucleic acids encompassed by the amended claims to comprise the relevant genus of nucleic acids of the present invention.

Therefore, Applicants submit that amended claim 1 and claims 2-18, which depend from claim 1, satisfy the written description requirement. Accordingly, Applicants respectfully submit that the Examiner's written description rejection has either been overcome or no longer applies, and request reconsideration and withdrawal of the rejection.

#### Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1-18 under 35 U.S.C. § 112, second paragraph, as being indefinite on various grounds. Applicants address each of the Examiner's rejections as follows.

Claim 1, and all claims that depend from claim 1, were rejected as being indefinite for recitation of the phrase, "a nucleic acid with the DNA sequence..." While not necessarily agreeing with the Examiner's reasoning, Applicants have amended claim

1 to recite, “a nucleic acid having the DNA sequence set forth in SEQ ID NO: 1...”

Accordingly, Applicants respectfully submit that claim 1, and all claims that depend from claim 1, are not indefinite.

Claim 1, and all claims that depend from claim 1, were also rejected as being indefinite for recitation of the phrase, “a combination of several of the nucleic acids stated in (a) to (g).” While not necessarily agreeing with the Examiner’s reasoning, Applicants have amended claim to read, “(f) a nucleic acid comprising at least two of the nucleic acids set forth in (a) to (e).” Applicants respectfully submit that claim 1, as amended, is not indefinite, and that the claim particularly describes a single nucleic acid comprising at least two of the nucleic acids set forth in the claim.

Claim 11 was rejected as being indefinite for recitation of the phrase, “a heterologous nucleic acid sequence suitable for expression and optionally secretion.” While not agreeing with the Examiner’s characterization of the claim, Applicants have amended claim 11 to more specifically point out the claimed invention. In particular, Applicants have amended claim 11 herein to recite, “...further comprising a heterologous nucleic acid sequence suitable to direct expression and optionally secretion of the polypeptide encoded by said isolated nucleic acid.” Support for claim 11, and for the amendments made to claim 11 can be found in the specification, and in particular, from line 25 on page 9 through line 27 on page 10. Accordingly, Applicants respectfully submit that claim 11 is not indefinite.

Claims 9, 11, 14 and 17 were rejected as being indefinite for recitation of the phrase, “suitable for expression.” While not agreeing with the Examiner’s characterization of the claims, Applicants have amended claims 9, 11, 14 and 17 to more specifically point out the claimed invention. In particular, Applicants have amended claim 9 herein to recite, “...further comprising a promoter suitable to control ~~for~~ expression of the polypeptide encoded by said isolated nucleic acid...,” claim 11 herein to recite, “further comprising a heterologous nucleic acid sequence suitable ~~for~~ to direct expression and optionally secretion of the polypeptide encoded by said isolated nucleic acid,” and claims 14 and 17 herein to recite, “in a host cell suitable for the expression of a polypeptide encoded by said nucleic acid molecule.” Applicants respectfully submit that claims 9, 11, 14 and 17, as amended, are not indefinite, as the claims specifically recite

the claimed invention. The skilled artisan would understand the intended scope of the claims.

Regarding claims 14 and 17, Applicants further respectfully assert that language directed to a “host cell suitable for expression” of a desired polypeptide is not indefinite for the following reasons. First, the skilled artisan would understand that a non-naturally occurring host cell “suitable for expression” is a host cell that has been modified such that the cell is useful for the controlled expression of one or more proteins. In particular, Applicants respectfully direct the Examiner’s attention to pages 1 and 2 of the specification, in the Background of the Invention, in which Applicants set forth characteristics and conditions that would qualify a cell to be “suitable” for protein expression.

Applicants respectfully remind the Examiner that MPEP § 2111.01 states that “the applicant may be his or her own lexicographer,” provided that the definition of a term in the specification of a patent application is not “repugnant” to the art-accepted use of the term. Applicants respectfully submit that the phrase “suitable for expression” as defined in the instant specification is not repugnant to the art-accepted use of the phrase.

Claims 14 and 16 were rejected as being indefinite for recitation of the phrase, “non-naturally occurring,” as it is the Examiner’s view that it is unclear how the skilled artisan “would discern if a cell were naturally occurring versus non-naturally occurring.” The Examiner has suggested that use of the term “recombinant” in the rejected claims would be remedial. While not necessarily agreeing with the Examiner’s reasoning, Applicants have amended claims 14 and 16 to recite a “recombinant cell.” Accordingly, Applicants respectfully submit that claims 14 and 16 are no longer indefinite for recitation of the phrase, “non-naturally occurring.”

Claim 16 was also rejected as indefinite for inclusion of both genus and species limitations in a single claim, and for recitation of the phrase, “such as” in the Markush group included in claim 16. Applicants have amended claim 16 such that the Markush group now recites, “a yeast cell, an insect cell, and a mammalian cell.” Applicants have added two new dependent claims, claims 34 and 35, to encompass the subject matter deleted from the amended claim 16. Specifically, claim 34 is directed to a yeast cell selected from the group consisting of a *Hansenula polymorpha* cell and a

*Saccharomyces cerevisiae* cell, and claim 35 is directed to a mammalian cell is selected from the group consisting of a CHO cell, a COS cell and a HeLa cell. Additionally, Applicants have removed the phrase, “such as” upon addition of new claims 34 and 35. Therefore, Applicants respectfully submit that claim 16, and dependent claims 34 and 35, are not indefinite.

Claims 15 and 16 were rejected as being indefinite for lack of the phrase, “the group consisting of...” prior to a Markush group. Applicants have amended claims 15 and 16 to recite “the group consisting of...” prior to the Markush group, and have amended the language within the Markush group such that the Markush group more particularly points out the members of the group. Accordingly, Applicants respectfully submit that claims 15 and 16 are no longer indefinite for containing improper Markush group format.

Claim 18 was rejected for recitation of the phrase, “naturally modified.” While not necessarily agreeing with the Examiner’s reasoning, Applicants have amended claim 18 to recite, “...is chemically modified or is post-translationally modified within said host cell.” Accordingly, Applicants submit that claim 18 is not indefinite, and that claim 18, as amended, specifically defines the scope of the claim.

Applicants respectfully submit that each and every one of the Examiner’s rejections of the claims under 35 U.S.C. § 112, second paragraph, have either been overcome, rendered moot, or no longer apply, and therefore, request reconsideration and withdrawal of the rejections. No new matter has been added by way of any amendments made to overcome the Examiner’s rejections.

#### Rejections Under 35 U.S.C. § 102(b)

The Examiner has set forth two rejections under 35 U.S.C. § 102(b), arguing that the present invention is anticipated by multiple separate prior art references. The Examiner rejected claims 1, 2, 7-9, 11, 12, 14, 15, 17 and 18 in detail, as being anticipated by Gray et al. (1990, Biochem. 29:376-383) and by Eberhard et al. (1996, The Plant J. 10:815-821). Both of the Examiner’s rejections are essentially based on the Examiner’s written description rejection, as described above. That is, in the Examiner’s view, because the claims essentially read on “any chorismate mutase from any



organism," the chorismate mutases disclosed in the Gray and Eberhard references anticipate the invention.

It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, in order for a rejection under 35 U.S.C. § 102(b) to be proper, each and every element of Applicants' invention must be disclosed by either the Gray reference or the Eberhard reference. However, the neither reference teaches each and every element of the presently claimed invention.

Applicants respectfully traverse the Examiner's rejection of claim 1, and claims 2, 7-9, 11, 12, 14, 15, 17 and 18, which depend from claim 1, and submit that the neither the Gray reference nor the Eberhard reference anticipates the claims. As described in detail above in Applicants' response to the Examiner's Written Description rejection, Applicants have amended claim 1 to remove all language directed to non-specific homologs, fragments and variants of SEQ ID NO:1. Specifically, Applicants have amended claim 1 to recite SEQ ID NO:1, complements of SEQ ID NO:1, nucleic acid sequences comprising SEQ ID NO:1, nucleic acid sequences that hybridize with such nucleic acids, and mutants of SEQ ID NO:1 wherein the mutant nucleic acids encode the same protein as does the SEQ ID NO:1 nucleic acid sequence, but differ in nucleic acid sequence from the wild type sequence due to the degeneracy of the genetic code. Neither the Gray reference, nor the Eberhard reference discloses or teaches SEQ ID NO:1, complements of SEQ ID NO:1, nucleic acid sequences comprising SEQ ID NO:1, nucleic acid sequences that hybridize with such nucleic acids, and mutants of SEQ ID NO:1 wherein the mutant nucleic acids encode the same protein as does the SEQ ID NO:1 nucleic acid sequence, but differ in nucleic acid sequence from the wild type sequence due to the degeneracy of the genetic code.

Therefore, Applicants respectfully submit that neither the Gray reference nor the Eberhard reference anticipates amended claim 1, nor does it anticipate claims 2, 7-9, 11, 12, 14, 15, 17 and 18, which depend from claim 1. Accordingly, Applicants

respectfully submit that the Examiner's rejections under 35 U.S.C. § 102(b) do not apply, and respectfully request reconsideration and withdrawal of both rejections.

Summary

Applicants respectfully submit that each of the Examiner's objections and rejections has either been overcome, rendered moot, or does not apply, and that each of claims 1-19, 34 and 35 is fully supported by the specification as originally filed and in condition for allowance. No new matter has been added to the application by way of the present amendments. Consideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,

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Enclosures: Petition for Three-Month Extension of Time and Accompanying Fee